REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO: [redacted] Churchgate Surgery, 119, Manchester Road, Denton, Manchester, M34 3RA:** **MacMillan Cancer Care, 89, Albert Embankment, London, SE1 7UQ:** **Takeda U.K. Limited, Building 3, Glory Park, Glory park Avenue, Wooburn Green, Buckinghamshire HP10 0DF:**
1	**CORONER** I am John Pollard, senior coroner, for the coroner area of South Manchester
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On 15th October 2015 I commenced an investigation into the death of Irene Anne Pearson dob 12th July 1941. The investigation concluded on the 18th January 2016 and the conclusion was one of **Misadventure**. The medical cause of death was 1a Opiate Toxicity .11 Carcinomatosis, Carcinoma Colon and Ischaemic Heart disease.
4	**CIRCUMSTANCES OF THE DEATH** **The deceased was diagnosed with terminal cancer of the colon which had then spread to various other organs (carcinomatosis). As part of her palliative care, she was prescribed Matrifen patches. She was ill-advised as to the level of medication which she needed and as to the precise effects of certain actions upon the delivery of such. On the 19th July 2015, at her home, she had a hot bath and was found dead in the bath, with the hot tap running. It is believed she was wearing the patch when she got into the bath.**
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – **1. The package leaflet of advice on the use of Matrifen is very extensive running to several pages of closely printed words. It is not until half way down the eighth page (and then contained in the middle of a 4th bullet point) that there is reference to the danger of taking a hot bath whilst wearing the patch. The Forensic Consultant Toxicologist gave evidence to me that heating of the body will cause an onrush of the delivery of the drug.** **(Takeda UK)** **2. Even when the said warning phrase is reached in the leaflet, it then refers to "a prolonged hot bath " without in any way defining the words "prolonged" or "hot".**

	These terms are easily open to subjective interpretation, which may lead to an unsafe usage environment. (Takeda UK) **3. I heard evidence that the Macmillan Nurses had advised the deceased to take a bath when preparing to remove the 'exhausted' patch so as to aid removal. The toxicologist pointed out that even when due for change, the patch contains (and therefore can release) a very considerable level of the drug. The advice to use this method of removal would therefore seem to be inherently potentially dangerous.(Macmillan Cancer Care)** **4. I was told that the Macmillan Nurses will prescribe additional opiate pain-control, but there seemed little or no liaison with the GP Practice as to the regulation of this.(Macmillan Cancer Care)** **5. The GP Practice's electronic notes of the attendances upon the patient were unclear and there appeared to be discrepancies between what was noted as prescribed by way of opiate patches, and what the patient actually had in her possession. The notes were on occasions 'scanty' in detail and the doctor giving evidence accepted this and told me that this was because they, as doctors, are limited to ten-minute appointments and they do not always have time properly to record their notes. (Churchgate Surgery)** **6. When HM Coroner asks for a full report of the care of the patient from the General Practitioner, it is insufficient (as in this case), for the practice simply to photocopy part of the patient's records. (Churchgate Surgery)**
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.
7	**YOUR RESPONSE** **You are under a duty to respond to those issues attributed to you in paragraph 5 of this report within 56 days of the date of this report**, namely by 15th March 2016. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the **Chief Coroner** and to the following Interested Persons namely [redacted] (Husband of the deceased). I have also sent it to **CQC**, [redacted] (consultant forensic toxicologist), **Mrs M.J. Leeming** (Senior Coroner Manchester West) and **Mr S. Nelson** (Senior Coroner Manchester North) who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**19.1.16** **John Pollard, HM Senior Coroner**